510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By:
Exactech, Inc.
2320 N.W. 66th Court
Gainesville, FL 32653

2. Contact:
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3. Product:
Exactech Optetrak® Unicondylar Knee

21 CFR Section 888.3530
Prosthesis, Knee, Femorotibial,
Semi-Constrained, Cemented
Metal/Polymer

Class II

Product Code HRY

Description:

The Exactech Optetrak® Unicondylar Knee system is comprised of six sizes of symmetric femoral components and six sizes of asymmetric (right and left side-specific) all-poly tibial components. These components articulate together and are used to replace a portion of the human knee joint that has been debilitated by injury or disease. Specifically, these components are used to replace the damaged biological articular geometry on the medial or lateral aspects of both right and left knees.

Intended Use:

The Exactech Optetrak® Unicondylar Knee System is intended for partial replacement of the medial or lateral articulating surface of the knee joint. The system is indicated for primary surgery in skeletally mature patients with one or more of the following clinical conditions:

- Non-inflammatory osteoarthritis, osteonecrosis and/or traumatic arthritis
- Functional deformity
- Tibial condyle or plateau fractures that are not manageable by other techniques
- Traumatic bone and/or cartilage lesions

All components are intended for cemented use only.

Technological Characteristics and Substantial Equivalence:

Like the Zimmer MG (K942263) and Link Endo-Modell (K944186) femoral components, the Exactech Optetrak Unicondylar femoral component is built from cobalt-chromium alloy (ASTM F-75). The DePuy Preservation (K010810) femoral component is also made from cobalt-chromium. The Exactech Unicondylar femoral component has both sagittal and coronal plane curvature, which is consistent with the predicate component femoral geometries.

Like all three predicate components, the Exactech Optetrak Unicondylar tibial component is built from Ultra High Molecular Weight Polyethylene - UHMWPE (ASTM-F648). The Exactech Optetrak Unicondylar tibial component has both sagittal and coronal plane curvature, which is consistent with the DePuy Preservation predicate device. This curvature is intended to reduce contact stresses and facilitate anatomic-like articulation kinematics, however, it does not impose excessive constraint on the femoral component.

Performance Testing:

Functional testing and engineering analysis was conducted to verify that the implant performance would be adequate for anticipated *in vivo* kinematic and loading conditions.

The testing and analysis data collected for the Exactech Optetrak Unicondylar Knee components demonstrated that they are compatible with the intended use and substantially equivalent to the referenced predicate devices.

Conclusions:

The Exactech Optetrak® Unicondylar Knee is substantially equivalent to similar devices existing in the market in materials of construction, dimensions, and performance characteristics. It has been determined to be an effective design and when used according to instructions for use, is a useful and valuable device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 - 2004

Ms. Lisa Simpson
Senior Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K040889
Trade/Device Name: Exactech Optetrak® Unicondylar Knee
Regulation Number: 21 CFR 888.3530
Regulation Name: Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: HRY
Dated: September 10, 2004
Received: September 13, 2004

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K04 0889

Device Name: **Exactech Optetrak® Unicondylar Knee**

Intended Use: The Exactech Optetrak® Unicondylar Knee System is intended for partial replacement of the medial or lateral articulating surface of the knee joint. The system is indicated for primary surgery in skeletally mature patients with one or more of the following clinical conditions:

- Non-inflammatory osteoarthritis, osteonecrosis and/or traumatic arthritis
- Functional deformity
- Tibial condyle or plateau fractures that are not manageable by other techniques
- Traumatic bone and/or cartilage lesions

All components are intended for cemented use only.

Prescription Use **X** or Over-the-counter Use _____
(Per CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040889